



CASE D0250 NP

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Audrey F. Sher  
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*Audrey F. Sher*  
Signature

March 29, 2004  
Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

DOWEYKO ET AL.

APPLICATION NO: 10/621,807

FILED: JULY 17, 2003

FOR: COMPOSITIONS AND METHODS INVOLVING NUCLEAR  
HORMONE RECEPTOR SITE II

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INFORMATION DISCLOSURE STATEMENT

Sir:

Applicants believe this paper is being filed before the mailing date of a first Office Action on the merits, and so under 37 C.F.R. §1.97(b)(3) no fees are required. If a fee is deemed to be required, the Commissioner is hereby authorized to charge such fee to Deposit Account No. 19-3880.

In accordance with 37 C.F.R. §1.56, applicants wish to call the Examiner's attention to the references cited on the attached form(s) PTO-1449.

Copies of these references are enclosed herewith when available in paper copy.

The RCSB Protein Data Bank References listed as 7AG-8AF are available through the Research Collaboratory for Structural Bioinformatics Protein Data Bank at <http://www.rcsb.org/pdb>.

The PIR Accession Numbers listed as 8AG-8AH are available through the Protein Information Resource at <http://pir.georgetown.edu>.

The Genbank Accession Numbers listed as 8AI- 9AA are available through the National Center for Biotechnology Information at <http://www.ncbi.nlm.nih.gov>.

The Examiner is requested to consider the foregoing information in relation to this application and indicate that each reference was considered by returning a copy of the initialed PTO 1449 form(s).

Respectfully submitted,

Bristol-Myers Squibb Company  
Patent Department  
P.O. Box 4000  
Princeton, NJ 08543-4000  
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Audrey F. Sher  
Attorney for Applicants  
Reg. No. 39,024

Date: *March 29, 2004*

## INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

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## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE
	AA						
	AB						
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## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	OFFICE	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	AM	WO 03/015692	2/27/03	PCT			<input type="checkbox"/>	<input type="checkbox"/>
	AN	WO 2004/009017	1/29/04	PCT			<input type="checkbox"/>	<input type="checkbox"/>
	AO						<input type="checkbox"/>	<input type="checkbox"/>
	AP						<input type="checkbox"/>	<input type="checkbox"/>
	AQ						<input type="checkbox"/>	<input type="checkbox"/>

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

	AR	Arriza, J.L. et al., "Cloning of Human Mineralocorticoid Receptor Complementary DNA: Structural and Functional Kinship with the Glucocorticoid Receptor", Science, Vol. 237, pp. 268-275 (1987)
	AS	Baldwin, Jr., A.S., "The transcription factor NF- $\kappa$ B and human disease", The Journal of Clinical Investigation, Vol. 107, No. 1, pp. 3-6 (2001)
	AT	Bamberger, C.M. et al., "Glucocorticoid Receptor $\beta$ , a Potential Endogenous Inhibitor of Glucocorticoid Action in Humans", The Journal of Clinical Investigation, Vol. 95, pp. 2435-2441 (1995)

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2AA	Bledsoe, R.K. et al., "Crystal Structure of the Glucocorticoid Receptor Ligand Binding Domain Reveals a Novel Mode of Receptor Dimerization and Coactivator Recognition", Cell, Vol. 110, pp. 93-105 (2002)
2AB	Bourguet, W. et al., "Crystal structure of the ligand-binding domain of the human nuclear receptor RXR- $\alpha$ ", Nature, Vol. 375, pp. 377-382 (1995)
2AC	Brandon, D.D. et al., "Genetic variation of the glucocorticoid receptor from a steroid-resistant primate", Journal of Molecular Endocrinology, Vol. 7, pp. 89-96 (1991)
2AD	Caldenhoven, E. et al., "Negative Cross-Talk between RelA and the Glucocorticoid Receptor: A Possible Mechanism for the Antiinflammatory Action of Glucocorticoids", Molecular Endocrinology, Vol. 9, No. 4, pp. 401-412 (1995)
2AE	Chakravarti, D. et al., "Role of CBP/P300 in nuclear receptor signalling", Nature, Vol. 383, pp. 99-103 (1996)
2AF	Coghlan, M.J. et al., "Synthesis and Characterization of Non-Steroidal Ligands for the Glucocorticoid Receptor: Selective Quinoline Derivatives with Prednisolone-Equivalent Functional Activity", J. Med. Chem., Vol. 44, pp. 2879-2885 (2001)
2AG	Da Silva, J.A. et al., "Optimizing Glucocorticoid Therapy in Rheumatoid Arthritis", Neuroendocrine Mechanisms in Rheumatic Disease, Rheumatic Disease Clinics of North America, Vol. 26, No. 4, pp. 859-880 (2000)
2AH	Danielsen, M. et al., "The mouse glucocorticoid receptor: mapping of functional domains by cloning, sequencing and expression of wild-type and mutant receptor proteins", The EMBO Journal, Vol. 5, No. 10, pp. 2513-2522 (1986)
2AI	Darimont, B.D. et al., "Structure and specificity of nuclear receptor-coactivator interactions", Genes & Development, Vol. 12, pp. 3343-3356 (1998)
2AJ	Diamond, M.I. et al., "Transcription Factor Interactions: Selectors of Positive or Negative Regulation from a Single DNA Element", Science, Vol. 249, pp. 1266-1272 (1990)
2AK	Eisenmann, G. et al., "Quand Les Cellules Scintillent", Le Technoscope De Biofutur, No. 151, p. 8 (1995)
2AL	Elmore, S.W. et al., "Nonsteroidal Selective Glucocorticoid Modulators: the Effect of C-5 Alkyl Substitution on the Transcriptional Activation/Repression Profile of 2,5-Dihydro-10-methoxy-2,2,4-trimethyl-1H-[1]benzopyrano[3,4-f]quinolines", J. Med. Chem., Vol. 44, pp. 4481-4491 (2001)
2AM	Evans, R.M., "The Steroid and Thyroid Hormone Receptor Superfamily", Science, Vol. 240, pp. 889-895 (1988)
2AN	Firestein, G.S. et al., "Signal Transduction and Transcription Factors in Rheumatic Disease", Arthritis & Rheumatism, Vol. 42, No. 4, pp. 609-621 (1999)

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	3AA	Francis, G.A. et al., "Nuclear Receptors and the Control of Metabolism", Annu. Rev. Physiol., Vol. 65, pp. 261-311 (2003)
	3AB	Giguère, V. et al., "Functional Domains of the Human Glucocorticoid Receptor", Cell, Vol. 46, pp. 645-652 (1986)
	3AC	Giguère, V. et al., "Identification of a new class of steroid hormone receptors", Nature, Vol. 331, pp. 91-94 (1988)
	3AD	Giguère, V. et al., "Orphan Nuclear Receptors: From Gene to Function", Endocrine Reviews, Vol. 20, No. 5, pp. 689-725 (1999)
	3AE	Grange, T. et al., "In vivo analysis of the model tyrosine aminotransferase gene reveals multiple sequential steps in glucocorticoid receptor action", Oncogene, Vol. 20, pp. 3028-3038 (2001)
	3AF	Green, S. et al., "Human oestrogen receptor cDNA: sequence, expression and homology to v-erb-A", Nature, Vol. 320, pp. 134-139 (1986)
	3AG	Greene, M.E. et al., "Isolation of the Human Peroxisome Proliferator Activated Receptor Gamma cDNA: Expression in Hematopoietic Cells and Chromosomal Mapping", Gene Expression, Vol. 4, pp. 281-299 (1995)
	3AH	Greschik, H. et al., "Structural and Functional Evidence for Ligand-Independent Transcriptional Activation by the Estrogen-Related Receptor 3", Molecular Cell, Vol. 9, pp. 303-313 (2002)
	3AI	Hager, L.J. et al., "Transcriptional regulation of mouse liver metallothionein-I gene by glucocorticoids", Nature, Vol. 291, pp. 340-342 (1981)
	3AJ	Hofmann, T.G. et al., "Various glucocorticoids differ in their ability to induce gene expression, apoptosis and to repress NF- $\kappa$ B-dependent transcription", FEBS Letters, Vol. 441, pp. 441-446 (1998)
	3AK	Hollenberg, S.M. et al., "Primary structure and expression of a functional human glucocorticoid receptor cDNA", Nature, Vol. 318, pp. 635-641 (1985)
	3AL	Huang, X. et al., "Elucidating the Inhibiting Mode of AHPBA Derivatives against HIV-1 Protease and Building Predictive 3D-QSAR Models", J. Med. Chem., Vol. 45, pp. 333-343 (2002)
	3AM	Jonat, C. et al., "Antitumor Promotion and Antiinflammation: Down-Modulation of AP-1 (Fos/Jun) Activity by Glucocorticoid Hormone", Cell, Vol. 62, pp. 1189-1204 (1990)
	3AN	Jones, D.C. et al., "Nuclear Receptor Peroxisome Proliferator-activated Receptor $\alpha$ (PPAR $\alpha$ ) Is Expressed in Resting Murine Lymphocytes", The Journal of Biological Chemistry, Vol. 277, No. 9, pp. 6838-6845 (2002)

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## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

4AA	Kalkhoven, E. et al., "Negative Interaction between the RelA(p65) Subunit of NF- $\kappa$ B and the Progesterone Receptor", The Journal of Biological Chemistry, Vol. 271, No. 11, pp. 6217-6224 (1996)
4AB	Kallio, P.J. et al., "Androgen Receptor-Mediated Transcriptional Regulation in the Absence of Direct Interaction with a Specific DNA Element", Molecular Endocrinology, Vol. 9, No. 8, pp. 1017-1028 (1995)
4AC	Kamei, Y. et al., "A CBP Integrator Complex Mediates Transcriptional Activation and AP-1 Inhibition by Nuclear Receptors", Cell, Vol. 85, pp. 403-414 (1996)
4AD	Kauppi, B. et al., "The Three-dimensional Structures of Antagonistic and Agonistic Forms of the Glucocorticoid Receptor Ligand-binding Domain", The Journal of Biological Chemistry, Vol. 278, No. 25, pp. 22748-22754 (2003)
4AE	Keightley, M.-C. et al., "Unique Sequences in the Guinea Pig Glucocorticoid Receptor Induce Constitutive Transactivation and Decrease Steroid Sensitivity", Molecular Endocrinology, Vol. 8, No. 4, pp. 431-439 (1994)
4AF	Keller, E.T. et al., "Inhibition of NF $\kappa$ B Activity through Maintenance of I $\kappa$ B $\alpha$ Levels Contributes to Dihydrotestosterone-mediated Repression of the Interleukin-6 Promoter", The Journal of Biological Chemistry, Vol. 271, No. 42, pp. 26267-26275 (1996)
4AG	Laudet, V. et al., Chapter 4: "Molecular mechanisms of transcriptional regulation", The Nuclear Receptor FactsBook, Academic Press, publ., pp. 42-61 (2002)
4AH	Laudet, V. et al., "GR", The Nuclear Receptor FactsBook, Academic Press, publ., pp. 345-367 (2002)
4AI	Lind, U. et al., "Functional Probing of the Human Glucocorticoid Receptor Steroid-interacting Surface by Site-directed Mutagenesis", The Journal of Biological Chemistry, Vol. 275, No. 25, pp. 19041-19049 (2000)
4AJ	Lubahn, D.B. et al., "The Human Androgen Receptor: Complementary Deoxyribonucleic Acid Cloning, Sequence Analysis and Gene Expression in Prostate", Molecular Endocrinology, Vol. 2, No. 12, pp. 1265-1275 (1988)
4AK	Mangelsdorf, D.J. et al., "Nuclear receptor that identifies a novel retinoic acid response pathway", Nature, Vol. 345, pp. 224-229 (1990)
4AL	Matias, P.M. et al., "Structural Evidence for Ligand Specificity in the Binding Domain of the Human Androgen Receptor", The Journal of Biological Chemistry, Vol. 275, No. 34, pp. 26164-26171 (2000)
4AM	Miesfeld, R. et al., "Characterization of a steroid hormone receptor gene and mRNA in wild-type and mutant cells", Nature, Vol. 312, pp. 779-781 (1984)
4AN	Miesfeld, R. et al., "Genetic Complementation of a Glucocorticoid Receptor Deficiency by Expression of Cloned Receptor cDNA", Cell, Vol. 46, pp. 389-399 (1986)

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**OTHER DOCUMENTS** (Including Author, Title, Date, Pertinent pages, Etc.)

5AA	Misrahi, M. et al., "Complete Amino Acid Sequence of the Human Progesterone Receptor Deduced from Cloned cDNA", Biochemical and Biophysical Research Communications, Vol. 143, No. 2, pp. 740-748 (1987)
5AB	Miura, T. et al., "Functional Modulation of the Glucocorticoid Receptor and Suppression of NF- $\kappa$ B-dependent Transcription by Ursodeoxycholic Acid", The Journal of Biological Chemistry, Vol. 276, No. 50, pp. 47371-47378 (2001)
5AC	Nakai, A. et al., "Characterization of a Third Human Thyroid Hormone Receptor Coexpressed with Other Thyroid Hormone Receptors in Several Tissues", Molecular Endocrinology, Vol. 2, No. 11, pp. 1087-1092 (1988)
5AD	Nolte, R.T. et al., "Ligand binding and co-activator assembly of the peroxisome proliferator-activated receptor- $\gamma$ ", Nature, Vol. 395, pp. 137-143 (1998)
5AE	Palvimo, J.J. et al., "Mutual Transcriptional Interference between RelA and Androgen Receptor", The Journal of Biological Chemistry, Vol. 271, No. 39, pp. 24151-24156 (1996)
5AF	Peltz, G., "Transcription factors in immune-mediated disease", Current Opinion in Biotechnology, Vol. 8, pp. 467-473 (1997)
5AG	Petkovich, M. et al., "A human retinoic acid receptor which belongs to the family of nuclear receptors", Nature, Vol. 330, pp. 444-450 (1987)
5AH	Reichardt, H.M. et al., "DNA Binding of the Glucocorticoid Receptor Is Not Essential for Survival", Cell, Vol. 93, pp. 531-541 (1998)
5AI	Reichardt, H.M. et al., "Repression of inflammatory responses in the absence of DNA binding by the glucocorticoid receptor", The EMBO Journal, Vol. 20, No. 24, pp. 7168-7173 (2001)
5AJ	Renaud, J.-P. et al., "Crystal structure of the RAR- $\gamma$ ligand-binding domain bound to all- <i>trans</i> retinoic acid", Nature, Vol. 378, pp. 681-689 (1995)
5AK	Reynolds, P.D. et al., "Cloning and Expression of the Glucocorticoid Receptor from the Squirrel Monkey ( <i>Saimiri boliviensis boliviensis</i> ), a Glucocorticoid-Resistant Primate", Journal of Clinical Endocrinology and Metabolism, Vol. 82, No. 2, pp. 465-472 (1997)
5AL	Ricote, M. et al., "The peroxisome proliferator-activated receptor- $\gamma$ is a negative regulator of macrophage activation", Nature, Vol. 391, pp. 79-82 (1998)
5AM	Ringold, G.M. et al., "Dexamethasone-Mediated Induction of Mouse Mammary Tumor Virus RNA: a System for Studying Glucocorticoid Action", Cell, Vol. 6, pp. 299-305 (1975)
5AN	Rochel, N. et al., "The Crystal Structure of the Nuclear Receptor for Vitamin D Bound to Its Natural Ligand", Molecular Cell, Vol. 5, pp. 173-179 (2000)

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## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

6AA	Rusconi, S. et al., "Functional dissection of the hormone and DNA binding activities of the glucocorticoid receptor", The EMBO Journal, Vol. 6, No. 5, pp. 1309-1315 (1987)
6AB	Scheidereit, C. et al., "The glucocorticoid receptor binds to defined nucleotide sequences near the promoter of mouse mammary tumour virus", Nature, Vol. 304, pp. 749-752 (1983)
6AC	Shiau, A.K. et al., "Structural characterization of a subtype-selective ligand reveals a novel mode of estrogen receptor antagonism", Nature Structural Biology, Vol. 9, No. 5, pp. 359-364 (2002)
6AD	Sierk, M.L. et al., "DNA Deformability as a Recognition Feature in the RevErb Response Element", Biochemistry, Vol. 40, pp. 12833-12843 (2001)
6AE	Stanbury, R.M. et al., "Systemic corticosteroid therapy — side effects and their management", Br. J. Ophthalmol., Vol. 82, pp. 704-708 (1998)
6AF	Stöcklin, E. et al., "Functional interactions between Stat5 and the glucocorticoid receptor", Nature, Vol. 383, pp. 726-728 (1996)
6AG	Takamatsu, Y. et al., "A New Method for Predicting Binding Free Energy Between Receptor and Ligand", Proteins: Structure, Function, and Genetics, Vol. 33, pp. 62-73 (1998)
6AH	Tanenbaum, D.M. et al., "Crystallographic comparison of the estrogen and progesterone receptor's ligand binding domains", Proc. Natl. Acad. Sci. USA, Vol. 95, pp. 5998-6003 (1998)
6AI	Valentine, J.E. et al., "Mutations in the Estrogen Receptor Ligand Binding Domain Discriminate between Hormone-dependent Transactivation and Transrepression", The Journal of Biological Chemistry, Vol. 275, No. 33, pp. 25322-25329 (2000)
6AJ	Van Hoorn, W.P., "Identification of a Second Binding Site in the Estrogen Receptor", J. Med. Chem., Vol. 45, pp. 584-589 (2002)
6AK	Vayssière, B.M. et al., "Synthetic Glucocorticoids That Dissociate Transactivation and AP-1 Transrepression Exhibit Antiinflammatory Activity <i>in Vivo</i> ", Molecular Endocrinology, Vol. 11, No. 9, pp. 1245-1255 (1997)
6AL	Wang, Y. et al., "A Second Binding Site for Hydroxytamoxifen within the Ligand-Binding Domain of Estrogen Receptor $\beta$ ", The Endocrine Society, Meeting June 2003, Presentation No. OR34-1, p. 106 (2003)
6AM	Wang, Z. et al., "Structure and function of Nurr1 identifies a class of ligand-independent nuclear receptors", Nature, Vol. 423, pp. 555-560 (2003)
6AN	Watkins, R.E. et al., "The Human Nuclear Xenobiotic Receptor PXR: Structural Determinants of Directed Promiscuity", Science, Vol. 292, pp. 2329-2333 (2001)

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	7AA	Weinberger, C. et al., "Identification of Human Glucocorticoid Receptor Complementary DNA Clones by Epitope Selection", Science, Vol. 228, pp. 740-742 (1985)
	7AB	Williams, S.P. et al., "Atomic structure of progesterone complexed with its receptor", Nature, Vol. 393, pp. 392-396 (1998)
	7AC	Yamamoto, K. et al., "Transcriptional Roles of Nuclear Factor $\kappa$ B and Nuclear Factor-Interleukin-6 in the Tumor Necrosis Factor $\alpha$ -Dependent Induction of Cyclooxygenase-2 in MC3T3-E1 Cells", The Journal of Biological Chemistry, Vol. 270, No. 52, pp. 31315-31320 (1995)
	7AD	Yang, K. et al., "Characterization of an ovine glucocorticoid receptor cDNA and developmental changes in its mRNA levels in the fetal sheep hypothalamus, pituitary gland and adrenal", Journal of Molecular Endocrinology, Vol. 8, pp. 173-180 (1992)
	7AE	Yang-Yen, H.-F. et al., "Transcriptional Interference between c-Jun and the Glucocorticoid Receptor: Mutual Inhibition of DNA Binding Due to Direct Protein-Protein Interaction", Cell, Vol. 62, pp. 1205-1215 (1990)
	7AF	Zhang, S. et al., "Role of the C Terminus of the Glucocorticoid Receptor in Hormone Binding and Agonist/Antagonist Discrimination", Molecular Endocrinology, Vol. 10, No. 1, pp. 24-34 (1996)
	7AG	RCSB Protein Data Bank Reference 1NHZ
	7AH	RCSB Protein Data Bank Reference 1LBD
	7AI	RCSB Protein Data Bank Reference 2PRG
	7AJ	RCSB Protein Data Bank Reference 2LBD
	7AK	RCSB Protein Data Bank Reference 1A28
	7AL	RCSB Protein Data Bank Reference 1DB1
	7AM	RCSB Protein Data Bank Reference 1E3G
	7AN	RCSB Protein Data Bank Reference 1A52

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8AA	RCSB Protein Data Bank Reference 1L2J
8AB	RCSB Protein Data Bank Reference 1BSX
8AC	RCSB Protein Data Bank Reference 1HLZ
8AD	RCSB Protein Data Bank Reference 1ILH
8AE	RCSB Protein Data Bank Reference 1KV6
8AF	RCSB Protein Data Bank Reference 1OVL
8AG	PIR Accession Number QRHUGA
8AH	PIR Accession Number A29613
8AI	GenBank Accession Number U87951
8AJ	GenBank Accession Number AF141371
8AK	GenBank Accession Number L13196
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	9AA	GenBank Accession Number X04435
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